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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/049,847	03/27/1998	SYLVIE BAY	102.166A	6142

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/049,847	BAY ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/12/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30,32,38,39,42-44 and 47-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30,32,38,39,42-44 and 47-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-28, 31, 33-37, 40-41 and 45-46 have been cancelled.

Claims 29-30, 32, 38-39, 42-44 and 47-50 are under consideration and examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 29-30, 32, 38-39, 42-44 and 47-50, as amended, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the Office actions of 1/30/03 and 7/14/04 and reiterated below.

The specification fails to provide a written description for a vaccine or immunogenic composition in a method effective against the huge scope of tumors using the huge scope of the

conjugate comprising a tumor antigen or its derivative. It is well known in the art that vaccination indicates a protective effect. The complex nature of tumors, let alone its cure, to date remains still elusive. For some tumors, the etiologic agent that causes said tumor remains undefined. To date agents believed to have therapeutic effect against tumors are only candidates or promising leads for said therapy. Example (3) in the specification, page 27 describes protection induce by the conjugate against murine adenocarcinoma in mice. There is no correlation of the results obtained from the specific antigen as applied to the specific tumor, adenocarcinoma, to the huge scope of the tumor antigen and tumors. The claims recite for several and numerous huge scope for the undefined variables such as the tumor antigen, or its derivatives and the tumors being prevented. Note the Dalgleish reference which discloses the "numerous problems which are encountered when an anti-tumor immune response is desired". Furthermore, the specification provides only a general description of the derivative. The exemplification with respect to this derivative is nil. The description is directed to a single tumor antigen, galactosyl-N-acetyl serine. There is no description or correlation of this single tumor antigen to the huge scope of a tumor antigen or a carbohydrate derivative of the tumor antigen. To satisfy a

written description requirement for a claimed genus a sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure indicates that the applicants have invented species sufficient to constitute the gen[us]. Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004).

Response to Arguments

Applicants incorporate their arguments of Nov. 16,2004 herein. Applicants further argue that the claims have now been limited to cancer as described in Example and believed to be directed to specific tumor antigens.

In reply, the response to the Nov. 16, 2004 arguments is also incorporated herein. Only claim 42 recites the tumor antigen as colon. The rest of the claims do not recite said tumor. See further the Kudak reference, newly submitted by applicants at page 12474, col. 2 which states "..immune response to nonpeptide substances, such as carbohydrates, although highly abundant on surfaces of…tumor tissues, remain poorly understood partly due to a lack of experimentation on ……probe structures…"

Claims 29-30, 32, 38-39, 42-44 and 47-50, as amended, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. [This is a new matter rejection.)

The claimed "carbohydrate content comprised between 37% to 90%(w/w)" is not supported in the as-filed specification. Applicants pointed out the support at page 8 with the accompanying highlighted section of said page. A review of page 8 does not reveal said carbohydrate content and the highlighted section is not on file.

Applicants' showing of comparative determination of the molecular ratio of the carbohydrate contain in the instant

conjugates with the prior art is unclear to the rejection it applies thereto.

Claim Rejections - 35 USC § 103

Claims 29-30, 32, 38-39, 42-44 and 47-50, as amended, are rejected under 35 U.S.C. 103(a) as being obvious over Chong et al (5,679,352) or Chong in combination with Jondal (5,807,559) for reasons set forth in the last Office action.

Response to Arguments

Applicants assert that claim 29 which contain the carbohydrate content is not obvious over Chong which does not recite said carbohydrate content.

In response, since the specification does not disclose said carbohydrate content hence, the argued limitation does not overcome the Chong reference. Be it as it may, as applicants state at page 6 of the instant REMARKS, the molecular weight(?) ratio of carbohydrate content is found in conventional glycoconjugates as evident from the newly submitted Kuduk reference. Hence, since Chong discloses said glycoconjugates, the determination of its molecular weight would be within the ordinary skill in the art. In showing unexpected results, the comparison should have been made with the Chong reference and not with a prior art applicants had selected.

Applicants assert that the Chong et al patent discloses dendrimeric conjugates which combine only peptide T and B-

epitopes and Chong et al does not disclose or suggest any synthetic conjugate wherein the B-epitope is included in a carbohydrate moiety. Beginning at line 65 of column 3 through line 67 of column 6, Chong et al exclusively discloses synthetic conjugates wherein B-cell epitope is only a peptide compound and particularly, one of the P1, P2 and P6 proteins from hemophilus influenza (HIV). It is clear from various portions of Chong et al particularly, line 62 of column 4 wherein B-cell epitope of the P1 protein is cited in line 8 of column 5 wherein the B-cell epitope of P2 is cited and in line 19 of column 5 wherein B-cell epitope of P6 is cited. When the PRP carbohydrate moiety is used in the dendrimeric structures of Chong et al, it is only as a carrier molecule as expressed by the term "PRP-carrier conjugate vaccine" in lines 50 to 51 of column 6. Moreover, even in the case where the PRP carbohydrate moiety included in several embodiments of the dendrimeric structures of Chong et al would induce some antibody response against PRP which is neither described nor taught in Chong et al. It would remain that the said antibody response would not consist an antibody response against the "carbohydrate tumor antigens."

In response, Chong at col. 3, lines 15-20 recites the immunogenic synthetic conjugate comprising synthetic PRP oligomers and the antigenic determinants of Hi outer membrane protein. Chong at col. 2, lines 55-65 discloses that the synthetic PRP-peptide conjugate vaccine enhanced protective

ability and T-cell priming, which would indicate that the PRP induces antibody (B-cell) responses. Thus, whether PRP is ***termed*** as a carrier is immaterial as the conjugate is known as shown by e.g., Fig. 1. Attention is drawn to Chong at col. 17, lines 27-32 which discloses that the synthetic glycoconjugate may be used to produce vaccines eliciting antibodies against proteins or oligosaccharide. Such vaccines may be used to induce immunity toward ***tumor cells***, or to produce antitumor antibodies. Since Chong positively teaches induction of immunity against tumor cells, it would be within one having ordinary skill in the art to determine the tumor to which the conjugate function as such. Applicants assert that the Jondal teachings do not overcome the deficiencies of the Chong et al patent since Jondal is exclusively interested in raising a cyctotoxic T-cell response against a carbohydrate moiety and teaches exclusively a peptide-carbohydrate conjugate that raises a CTL response. One skilled in the art would have found absolutely no motivation to use any of the carbohydrate moieties disclosed by Jondal in the dendrimeric structures disclosed by Chong et al because he would not have foreseen that an effective antibody response might be raised against carbohydrate moieties.

In response, the disclosure of Jondal at col. 10, Table 1 supports the findings of Chong. Jondal discloses a conjugate of protein and tumor or bacterial antigen effective as anti-tumor or anti-bacterial antigen i.e., depending upon the vaccine or

immunity one desires i.e., whether an antitumor or antibacterial vaccine. The important aspect of the conjugation of protein-polysaccharide conjugates is the desire to elicit both T and B cells responses. Accordingly, the teachings of Chong, alone or in combination with Jondal render the claimed invention prima facie obvious.

Double Patenting

Claims 29, 30, 32 and 42 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,676,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant broad conjugate with B define as a carbohydrate of a tumor antigen or derivative encompasses the specific conjugate of the '946 Patent.

Response to Arguments

Applicants state that a terminal disclaimer is concurrently submitted with instant response.

In reply, the terminal disclaimer is not on file. Hence, the rejection is maintained.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571)272-4517. The fax phone number for the organization where this application or proceeding is assigned is(571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

July 17, 2006